

# Responsible Research Guidelines

Actual fraud in research is rare, however, negligence in the conduct of biomedical research is unfortunately not uncommon. This document represents a set of guidelines (not mandates) that will explicitly identify acceptable and desirable research procedures and practices; conversely, it can also be used as the basis for identification of unacceptable research practices. Hopefully, these guidelines can serve as the Indus upon which individual investigators, departments and research units can formulate their own guidelines to insure quality and integrity of research.

Loyola University of Chicago, Stritch School of Medicine, promulgates the following guidelines for investigators and scientific research.

## I. SUPERVISION OF RESEARCHERS

A. Almost all incidences of fraud, negligence or misconduct can be traced to a lack of adequate supervision, especially of new investigators. It can not be emphasized enough that if adequate preceptor supervision is present in a research unit, fraud negligence or misconduct is unlikely to occur. Thus, adequate supervision of all aspects of research data gathering, both clinical and bench, interpretation of data and publication practice is the primary barrier and ultimate deterrent to scientific misconduct.

### 1. SPECIFIC RECOMMENDATIONS

- a. There should be a well-delineated line of supervision for every junior investigator – this implies specific assignment and responsibility for junior investigators to a senior member in the research unit.
- b. The number of junior investigators assigned to a senior member should not exceed a reasonable number; that is, the responsible faculty member must be able to provide significant oversight, guidance and input for each investigator assigned to him/her. This ratio will vary from unit-to-unit depending on the types and volume of research being done within it. An area of special concern and need for vigilance is the conduct of clinical studies where junior investigators are, in turn, in charge of technical and nursing gather patient data of a subjective nature.
- c. Some form of informal, ongoing peer review process should be implemented in each research unit. The format is variable, there can be periodic conferences, seminars, staff meetings, etc.; but the continual exposure of departmental or research unit faculty to the progress of investigators within it is critical.

d. Access to current governmental and institutional requirements for the conduct of responsible research (IACUC, IRB, IBC) must be facilitated by both the department and the research support services.

e. Data gathering, storage and disposition. In the majority of allegations of misconduct, the investigator has had his/her position of credibility considerably eroded by the inability to provide verifiable data. Accurate, recorded and rapidly accessible research data is not only the keystone of science, but also the well spring of documentation in the event of an accusation of impropriety. An error can be relabeled misconduct when primary observations cannot be documented. It is recommended that custody of all original laboratory data must be retained by the primary investigator. He/she, not technical support, or clerical is responsible for it. The length of time for preservation of original data will remain the province of the departmental or research unit Chief. Data should be available for as long as there is a reasonable need to refer to it; this interval will vary, a minimum of five years is recommended. Original experimental results should be maintained in bound books and/or a secure and redundant computer format. Computer and machine print-outs should be retained as a hard copy to a data book. If original data is kept solely in a computer format, it is recommended that a log book of experiments by date with personnel involved should be kept in a hard copy format. Original hard copy data (at least a log book) may be, in the most adverse investigational situation, the only acceptable verifiable evidence.

## II. AUTHORSHIP

The "publish or perish" motivation can lead to serious misconduct. Adequate supervision of research faculty is the key to preventing scientific misconduct. A second and very effective reinforcing mechanism to deter misconduct is developing means to guarantee responsible authorship. Several well-documented instances of misconduct have involved junior investigators as first authors on numerous multi-author documents. The co-authors are usually unaware of fraudulent practices or misconduct and subsequently suffer adverse consequences in the face of eventual retraction. We affirm the basic principle that stated elsewhere-the only reasonable criterion for authorship of a manuscript is that the author has made a significant intellectual or practical contribution to the body of the work. The definition of "reasonable" stems from pragmatics of common sense and ethical principle, but should be stated explicitly and acted on consistently.

In an effort to promote this concept, the school supports the designation of a "responsible" author. This individual would usually be the senior author of a multiple author manuscript, but in practice many times this is not the case. The responsible author would be held accountable for methods and results in the work. The responsible author is identified as the first author unless the phrase "to whom correspondence should be addressed" is associated with an author other than the first author. In this case, the author "to whom correspondence should be addressed" is considered the responsible author. The responsible author must be prepared to provide a brief description of the role of all co-authors (if any) in any publication, if such is requested by the journal to which the

manuscript is submitted, or by a department head or other administrative official of LUMC.

### III. PUBLICATION

As long as the biomedical academic community of young faculty perceive the need to "publish or perish", a strong incentive that could foster possible misconduct in the form of publication practices that will amplify an individuals bibliography will be operative. This issue can not be resolved by dictate or even faculty consensus, but must be resolved by a firm University commitment to "publish less but better" science using the CART as the vehicle for promulgation of that concept.